Receipt date: 11/20/2009

Sheet

Equivalent of Form PTO/SB/08A (09-06)

Fourth Supplemental INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Substitute for form 1449/PTO

(Use as many sheets as necessary)

	Equivalent of Form 1 Crobrook (05-00)			
Complete if Known				
Application Number	10/555,343			
Filing Date	(§ 371 Date) November 1, 2005			
First Named Inventor	KATO et al.			
Art Unit	1614			
Examiner Name	Craig D. Ricci			
Attorney Docket Number	1089.0590000/MAC			

			U.S. PATENT D	OCUMENTS	
Examiner Cite Initials No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Number-Kind Code ^{2 (If Known)}		Typhicall of Olica Bounding	or Relevant Figures Appear
	US2	6,284,277 B1	09-04-2001	Bouloumie et al.	

	FOREIGN PATENT DOCUMENTS						
	Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where	
			Country Code ³ Number ³ Kind Code ⁵ (if known)			Relevant Passages or Relevant Figures Appear	T ⁶
Not :	in Engl	ish FP12		07.12.1000	Sanofr Synthelabo		
		1112	J1 11 307343		Danon-Bynthelabo		
							$\vdash\vdash$
	<u> </u>						\vdash

1043749v1

Examiner Signature	/Crain Ricci/	Date Considered	03/25/2010
Signature	/Craig Ricci/	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Receipt date: 11/20/2009

Equivalent of Form PTO/SB/08B (09-06) Substitute for form 1449/PTO Complete if Known **Application Number** 10/555,343 Fourth Supplemental Filing Date (§ 371 Date) November 1, 2005 INFORMATION DISCLOSURE First Named Inventor KATO et al. STATEMENT BY APPLICANT Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Craig D. Ricci Sheet of Attorney Docket Number 1089.0590000/MAC

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL21	Lückel, B., et al., "A Strategy for Optimizing the Lyophilization of Biotechnological Products," Pharm. Sc. 3(1): 3-8, The Royal Pharmaceutical Society of Great Britain, London, England, (January, 1997)	-
	NPL22	Roberts, C.,J. et al., "Engineering Pharmaceutical Stability with Amorphous Solids," AIChE Journal 48(6): 1140-1144, The American Institute of Chemical Engineers, New York, (June, 2002)	
	NPL23	Telang, C. et al., Effective Inhibition of Mannitol Crystallization in Frozen Solutions by Sodium Chloride," Pharm. Res. 20(4): 660-667, Kluwer Academic/Plenum publishers, Dordrecht, The Netherlands, (April, 2003)	
		-	

1043754_1.DOC

Examiner	/Craia Riosi/	Date	02/25/2010
Signature	/Craig nicci/	Considered	03/23/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and